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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/423,943      | 03/08/00    | SAMPATH              | K CIBT-P01-570      |

028120  
ROPES & GRAY

HM22/1023

ONE INTERNATIONAL PLACE  
BOSTON MA 02110-2624

EXAMINER

ANDRES, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/423,943

Applicant(s)

SAMPATH ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7 and 29-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 2 August 2001 in paper no. 12 is acknowledged. Claims 1-122 are pending in this application. Claims 6,7, and 29-122 are withdrawn from consideration as being drawn to a non-elected invention or species. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Election/Restrictions***

2. Applicant states that Applicant assumes that allowance with respect to one species will result in the allowance of the generic claim encompassing that species without examination of non-elected species on the merits. However, what was stated in the restriction requirement was that

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. ...

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Allowance with respect to one species therefore does not implicitly result in the allowance of a generic claim. No claim will be allowed without examination commensurate with the full scope of the claim language.

#### ***Claim Rejections/Objections Withdrawn***

3. The objection to the disclosure is withdrawn in response to Applicant's amendment.

4. The rejection of claims 2 and 4 under 35 U.S.C. 112, second paragraph is withdrawn in response to Applicant's clarification.

#### ***Claim Rejections Maintained/New Grounds of Rejection***

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5. The rejection of claims 1-5, 12-14, 20, and 23-28 under 35 U.S.C. 102(b) as anticipated by Rueger et al., WO 94/03200, is maintained.

Applicant argues that Rueger et al. does not teach a permissive, intentionally induced lesions. Applicant further argues that Rueger et al. teaches only administration at the site of the lesion.

Applicant's arguments have been fully considered but have not been found to be persuasive. Rueger et al. does teach animal models in which the lesions are intentionally induced. On p. 90, transection of the sciatic nerve is taught. On p. 92, crushing of the optic nerve is taught. In addition, the genetic or environmental damage taught on p. 99, as cited by Applicant, is exemplary only. Rueger et al. also teaches systemic administration on pages 55-58. Thus, Rueger et al. teaches animal models with intentionally induced lesions for purposes of evaluation and teaches systemic administration, anticipating the limitations of the instant claims.

6. The rejection of claims 8-11, 15-19, 21, and 22 under 35 U.S.C. 103(a) as unpatentable over Rueger et al. is maintained.

Applicant argues that Rueger et al does not teach the basic features of the claims, in particular the site of administration and the method of creating the defect.

Applicant's arguments have been fully considered but have not been found to be persuasive. Rueger et al. teaches both systemic administration and intentionally induced lesions, as discussed above. Rueger et al. also teaches administration at different time points on p. 93. In addition, as stated in the previous office action, evaluation of potential therapeutics in compromised animals is art standard and is thus an obvious modification of the methods taught by Rueger et al. Evidence that such evaluation is in fact art standard was provided in the

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previous office action by reference to a chapter by Benet in Sheiner in a textbook, The Pharmacological Basis of Therapeutics. Thus it would have been obvious to one of ordinary skill in the art to use the methods of Rueger et al. to evaluate therapeutic agents at different times and in compromised animals, because Rueger et al. explicitly suggests different time points, and Benet and Sheiner teaches altered effects of therapeutics in disease states.

7. The rejection of claims 1-5 and 8-28 under 35 U.S.C. 103(a) as unpatentable over Wang et al. is maintained.

Applicant argues that Wang et al. is limited to a process for using BMPs in treatment and is not directed to a process for evaluating candidate morphogens. Applicant further argues that Wang et al. teaches only application at the site of the defect.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous office action, Wang et al. teaches evaluation of BMP-2 and, on p. 8, teaches intravenous administration. Wang does not explicitly teach a method of evaluating morphogens, and intravenous administration is not taught as the preferred embodiment. However, the courts have held that

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom. In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

Wang et al. teaches success with other BMP molecules, and teaches that BMPs are members of a large family of related molecules. Wang et al. also teaches evaluation of dosages based on "condition..., time, and method of administration" (p. 7). Thus Wang et al. contemplates molecules other than BMP-2, contemplates other means of administration, and teaches evaluation strategies. It would thus have been obvious for one of ordinary skill in the art to

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apply the methods of Wang et al. to evaluate other morphogens, because one of ordinary skill would expect to find other useful molecules. It would further have been obvious to one of ordinary skill to use intravenous administration, because Wang et al. explicitly teaches such administration.

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.


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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[yvonne.eyler@uspto.gov\]](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
October 15, 2001

  
YVONNE EYLER, PH.D  
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